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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

RE: [Docket No. 99D-0296] FDA/HHS: Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products

Merck & Co., Inc. is a leading worldwide, human health product company. Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the most important pharmaceutical products on the market, today.

In the course of bringing our product candidates through developmental testing and clinical trials, Merck scientists regularly meet with CDER and CBER staff to address scientific and procedural issues, so we are directly affected by the *Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products*.

We commend FDA staff for taking this important step forward in improving communications about meetings. This *Draft Guidance* should improve the understanding of obligations of both parties during meeting preparation, which in turn should contribute to more efficient and effective meetings during the critical periods of product development. The *Draft Guidance* clarifies roles of both sponsors and FDA staff, as well as the paperwork and time requirements associated with requesting and organizing a meeting. Although a process similar to this has been followed *informally* by some industry companies and FDA staff, in the past, meeting expectations varied depending on the level of communications between participating parties. Now that both FDA staff and sponsors of new drug applications will be working from the same set of operating principles, meetings logistics should be handled more efficiently and expectations for meaningful outcomes should be more consistent. This will facilitate drug development timelines if meetings are scheduled at the earliest possible time point within the allowable timeframes, rather than push the limit of time available in the *Draft Guidance*, thereby maximizing its practical impact at implementation.

We look forward to formalization of these meeting procedures. We also encourage FDA to periodically evaluate the results of these improvements and make mid-course corrections during their implementation, as appropriate.

Sincerely,

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